

AMMENDMENTS TO THE SPECIFICATIONS:

Under **DESCRIPTION**

Please replace *Background of the Present Invention*, **Paragraph [0002]** with the following amended paragraph:

[0002] Obstructive Sleep Apnea, or OSA, occurs when the airway becomes blocked due to a collapse of the soft tissue in the back of the throat and tongue, or enlarged tissue in the tonsils and adenoids. When the patient's airway becomes blocked, they are not able to take a breath. Because the brain and heart are deprived of oxygen, blood pressure and heart rate increases can put the OSA patient at risk for heart attack and stroke. The breathing pauses can happen hundreds of time during the night, causing a snowball effect that leads to lack of energy and daytime sleepiness. Obstructive Sleep Apnea is the most common type. It is well known among sleep disorder physicians that, as either can cause an apnetic event, controlling the positions of both the tongue and the soft palate relative to each other is paramount in successfully addressing this condition.

Please replace *Background of the Present Invention*, **Paragraph [0005]** with the following amended paragraph:

[0005] The present invention, however, is concerned with addressing *obstructive* sleep apnea and snoring, and therefore the use of the phrase "sleep apnea" will heretofore be used to mean obstructive sleep apnea. Generally speaking, sleep apnea is caused by the relaxation of the muscles controlling the soft tissue and the tongue. The soft tissue then drapes down into the airway and vibrates as air passes it while the patient breathes, causing the sound that we call snoring. As the muscles relax further, and if the soft tissue is in close proximity with the back of the tongue, the soft tissue may close against the back of the tongue, thereby causing an occlusion, or a blocking of the airway. When the controlling muscles in the tongue relax during sleep, and especially when the patient is in the prone position, the tongue may roll back decreasing the distance between the back of the tongue and the soft tissue exacerbating the situation. In addition, the tongue may recede back far enough to close against the back of the throat, thereby causing its own apnetic event.

Please replace *Background of the Present Invention*, **Paragraph [0009]** with the following amended paragraph:

[0009] However, Hart is deficient in a number of aspects that ultimately prove it disadvantageous in managing sleep apnea. First Hart describes a mouthpiece that is rigid and custom molded to fit the wearer's oral cavity. This necessitates an expensive process of taking impressions and making molds requiring physician and laboratory expenses. In addition, time must be spent by a physician in fitting the device and making final changes and adjustments. Second, then, the resultant device by its very design is maximally intrusive as it fills the entire oral cavity with a hard, inflexible, foreign object which when inserted into the oral cavity will trigger the body's natural reflex to reject or expel the device once the conscious control by the individual is lost in sleep. The extent to which the device is not in the oral cavity represents a total lack of treatment of sleep apnea.

Finally, and most importantly, Hart does not disclose, or teach, of the need for the presence of any component designed to affect the action, or position, of the tongue. While using the Hart device, when the wearer falls asleep and the tongue muscles relax, the tongue is free to roll back against the back of the throat thereby causing an occlusion, or obstructive apnea.

Please replace *Summary of the Present Invention*, **Paragraph [0011]** with the following amended paragraph:

[0011] The Present Invention, in the preferred embodiment, overcomes the deficiencies listed above by providing a universal, adjustable, flexible, comfortable, and inexpensive device that is unique against the prior art in that it addresses simultaneously both organs within the oral cavity which contribute to, or cause, obstructive sleep apnea. The operative components of the device are shaped and configured so that the presence of one increases the effectiveness of the other creating a synergistic effect not included, anticipated, or taught within in the prior art.

Please replace *Summary of the Present Invention*, **Paragraph [0012]** with the following amended paragraph:

[0012] In one embodiment, the device comprises a mouthpiece member, a tube member adjustable in length, and an attachment member. The mouthpiece member comprises a resilient material such as soft silicone or rubber. Obviously the tube member has a superior (top) surface and inferior (bottom) surface, is affixed at a first end to the mouthpiece member and extends rearward towards the soft palate at the rear of the oral cavity of the wearer. The end of the superior surface supports soft palate and defines an opening through which air can pass freely. The inferior surface rests against the top of the tongue providing stability to the unit and inhibiting movement of the tongue into the airway. The attachment member (retaining strap) is attached to the mouthpiece member at two lateral locations.

Please replace *Summary of the Present Invention*, **Paragraph [0013]** with the following amended paragraph:

[0013] In another embodiment, the device comprises a mouthpiece member, a tube member, a palate member adjustable in length, and an attachment member. The mouthpiece member comprises a resilient material such as soft silicone or rubber. The tube member having a superior (top) surface and inferior (bottom) surface, is affixed at a first end to the mouthpiece member and extends rearward, the second end terminating just before ending just before the teeth. The palate member, having a superior surface and an inferior surface, is sufficiently adjustable in length for the posterior end of the palate member to reach, reside under, and lift the soft palate at the rear of the oral cavity of the wearer and define an opening through which air can pass freely. The inferior surface rests against the tongue providing stability to the unit and inhibiting movement of the tongue. The attachment member (retaining strap) is attached to the mouthpiece member at two lateral locations.

Please replace *Summary of the Present Invention*, **Paragraph [0014]** with the following amended paragraph:

[0014] In a third, and preferred embodiment, the oral device comprises a mouthpiece member, a tube member, a palate member, a tongue member, and an attachment member (retaining strap). The mouthpiece is comprised of a resilient material such as soft silicone or rubber. Both the soft palate member and tongue member are independently adjustable in length and extend rearwards from the mouthpiece past the teeth and towards the rear of the oral cavity of the user, the top of the palate member providing the superior surface and the bottom of the tongue member providing the inferior surface of the device. The palate member is shaped and configured so that a portion of its length rests against the top surface of the tongue member thereby providing stability to, and increasing the stability of, both components. The soft palate member then curves upwards and rearwards to engage and lift the soft tissue. The tongue member continues rearward, then curving downward to end slightly below and behind the tongue, thereby inhibiting rearward movement of the tongue. The space between the bottom of the palate member and the top of the tongue member at the rear of the oral cavity defines an opening through which air can pass freely. The attachment member is attached to the mouthpiece member at two lateral locations.

Please replace *Detailed Description of the Present Invention, Paragraph [0023]* with the following ammended paragraph

[0023] Attachment(retaining) member 16 is preferably affixed to mouthpiece at attachment points as shown with attachment/set screws 42. Attachment (retaining) member 16 comprises a flexible, resilient band of braided or ribbed elastic material which wraps around the head of the wearer to further stabilize the unit, and hold it in the proper position.

Please replace *Detailed Description of the Present Invention, Paragraph [0024]* with the following ammended paragraph.

[0024] Tube member 14 is inserted into and extends through mouthpiece member 12 to define openings 18 and 20. This allows for the free transfer of air between the outside environment and the oral cavity and ultimately the lungs of the wearer and visa versa. The transfer of air is represented by A and B; Arrow A indicating transfer of air into the oral cavity and lungs of the wearer, and Arrow B the tranfer of air out of the oral cavity and lungs of the wearer.

Please replace *Detailed Description of the Present Invention, Paragraph [0027]* with the following ammended paragraph.

[0027] Tube 14 is affixed to mouthpiece 12 and held in position by attachment/set screws 42 which extend through mouthpiece member 12 and into tube member 14. The depth to which tube 14 extends into the oral cavity can be adjusted by loosening attachment/set screws, sliding tube 14 forwards or backwards, and then tightening attachment/set screws. By this means, the necessary depth to which tube 14 must enter the oral cavity to reach and support the soft tissue in oral cavities of persons of varying sizes can be attained.

Please **DELETE** all information contained within *Detailed Description of the Present Invention, Paragraph [0030]*.

Please **DELETE** all information contained within *Detailed Description of the Present Invention, Paragraph [0031]*.

Please replace *Detailed Description of the Present Invention, Paragraph [0032]* with the following ammended paragraph.

[0032] In a second embodiment of oral device 10, as illustrated in FIG. 3, it is contemplated that the length of tube member 14 can be drastically reduced and not project past the teeth of the wearer. Palate member 44 is attached to tube member 14 using slot 52, clamp 48, and a set screw(not shown) 49 to enable adjustment to the necessary length for the declined posterior end 50 of palate member 44 to reach and support the soft tissue at the rear of the oral cavity of users of varying sizes.

Please replace *Detailed Description of the Present Invention, Paragraph [0033]* with the following amended paragraph.

[0033] Since tube member 14 does not extend posteriorly past the teeth of the wearer, air is drawn into and dispersed throughout the entire oral cavity, as would be the case in natural breathing. This reduces the incidence of dryness and/or scratchiness that tends to occur if the airstream into the oral cavity is more focused on a single spot on, or area of, the mucosal tissue. An additional benefit is that as tube 14 is replaced by palate member 44 which is a flat component approximately 1/16" inch thick. Less space is taken up by the components within the oral cavity, it is less intrusive and uncomfortable, and the wearer is more easily acclimated to using the device.

Please replace *Detailed Description of the Present Invention, Paragraph [0034]* with the following amended paragraph.

[0034] Preferably, palate member 44 is made of a flexible, non-corrosive, non-porous material such as plastic, rubber, coated aluminum, and is adjustable to attain sufficient length for opposing end 50 to reside under the soft palate of the wearer. It is contemplated that palate member may be bent into shape for a particular wearer. Palate member 44 may also include an anchoring/adjustment mechanism which is represented as slot 52 used in conjunction with clamp 48 and a set screw(not shown). In this embodiment, the soft palate lifter 50 located at the posterior end of the superior surface of palate member 44 supports the soft tissue when the wearer sleeps and helps to ensure the patency of the airway. At the same time, the inferior surface of palate member 44 rests atop the tongue thereby inhibiting movement of the tongue into the airway. This process of preventing the collapse of the soft tissue while inhibiting the movement of the tongue also prevents the tissues from vibrating, and so alleviates snoring.

Please replace *Detailed Description of the Present Invention, Paragraph [0035]* with the following amended paragraph.

[0035] A third embodiment of oral device 10 is illustrated in FIG. 4. In the third, which closely resembles the second embodiment described above, the inferior surface palate member 44 which rests against the tongue and inhibits movement of the tongue, is separated from palate member 44 so as to make it independently adjustable, and to enable changing the length to make it more effective in inhibiting movement of the tongue. It is now represented as tongue member 54. Tongue member 54 may contain an anchoring/adjustment mechanism similar to that used for palate member 44 utilizing slot 52B, clamp 48B, and a set screw (not shown). Tongue member 54 is preferably made of the same material and possesses the same characteristics as palate member 44, and is adjustable to attain sufficient length to extend posteriorly to reach the back of the tongue of wearer of different sizes. Posterior end of tongue member 54 is curved downwards so as to follow the curvature of the tongue and end below and behind the back of the tongue. In this embodiment, the superior surface of soft palate lifter 50 supports the soft tissue in the retroglossal area of the wearer, while the inferior surface of tongue member lays atop the tongue and inhibits movement of the tongue, especially from retracting rearward towards the soft palate and the back of the throat.

Please replace *Detailed Description of the Present Invention, Paragraph [0035]* with the following amended paragraph, continued:

It is important to note here that the intended use of tongue member 54 is not to depress or exert downward pressure on the tongue. It is meant only to retain the tongue in its most natural position as when the wearer is awake.

Please replace *Detailed Description of the Present Invention, Paragraph [0036]* with the following amended paragraph:

[0036] The unique shape, configuration, and combination of palate member 44 and tongue member 54 are critical in the performance of this embodiment of oral device 10. By working in unison in this way, a synergistic effect is created not found in the prior art. The presence, shape, and configuration of soft palate member 44 enhances the effectiveness of tongue member 54 by contributing to the stability and proper positioning of tongue member 54 against and behind the tongue, and the presence, shape, and configuration of tongue member 54 enhances the effectiveness of palate member 44 by contributing to the stability and proper positioning of palate member 44 in supporting the soft palate. This is illustrated in FIG 6. Palate member 44 is shaped and configured to rest on the superior surface of tongue member 54 at location 55. This ensures that distance 56 between the inferior surface of palate lifter 50 and the superior surface of tongue member 54 will be maintained despite any upward or downward movement of posterior end of the device due to changes in the position of the tongue or jaw during sleep. For example, if tongue member 54 was to rise due to upward pressure from the tongue, palate lifter 50 would rise also and both components would maintain their relative positions to each other, thus always maintaining distance 56 which defines an opening that ensures the patency of the airway. The illustrated shape and configuration of palate member 44, or a similar shape and/or configuration, defeats the effect of leverage which, if palate member 44 was not supported by tongue member 54 at location 55, would weaken the structure of the device at the posterior end causing distance 56 to more easily collapse and diminish the patency of the airway.

Please replace *Detailed Description of the Present Invention, Paragraph [0037]* with the following amended paragraph:

[0037] While only those embodiments set forth above have been described in detail, other configurations and embodiments may come to exist in the evolution of Device 10 within the spirit and scope of the present invention.